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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,709

10/30/2003

Edward W. Merrill

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EXAMINER

BERMAN, SUSAN W

ART UNIT

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1796

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/696,709	<b>Applicant(s)</b> MERRILL ET AL.	
	<b>Examiner</b> /Susan W. Berman/	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 124-134 is/are pending in the application.
- 4a) Of the above claim(s) 128-134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 124-127 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5-20-08, 6-3-09</u> . | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05-28-2009 has been entered.

***Response to Amendment***

The rejection of claims 124-127 under 35 U.S.C. 112, first paragraph, is withdrawn in response to the claim amendment replacing “pre-annealing” with “pre-heating”.

***Response to Arguments***

Applicant's arguments filed 05/28/2009 have been fully considered but they are not persuasive.

In response to applicant's arguments regarding the meaning of “pre-annealing”, applicant is reminded that claim terms must be fully supported by the original disclosure and not by what is “generally regarded” in the art. Applicant has not disclosed the term “pre-annealing” or a definition of “pre-annealing” within the instant specification to support recitation of “pre-annealing” in the claims. However, applicant is entitled to employ the language found in the instant specification, i.e “pre-heating” at temperatures and for time periods disclosed in the instant specification, and to argue that it reads on “pre-annealing” as disclosed in prior art documents, such as Saum et al ‘540.

With respect to applicant's arguments that the instant disclosure on page 30, lines 8-12, that heating is maintained at a preferred temperature for the specified time period, applicant is invited to employ the language referred to in the claims and to point out that the definition of annealing in the Saum et al Patent '540 in column 6, lines 34-41 overlaps by definition.

With respect to applicant's argument regarding the order of steps with respect to "pre-annealing", now "pre-heating", irradiation and quenching, and lack of a recited cooling step, it is noted that the claims require "irradiating the UHMWPE preform" without mention of whether the irradiating takes place before or after "pre-heating" and/or quenching free radicals. It is further noted that the step of quenching free radicals in the UHMWPE perform does not mention whether pre-heating and/or irradiating take place before or after the quenching step.

Shalaby et al and Sun et al: Applicant argues differences between the disclosure of Shalaby et al and the instantly claimed method that are not persuasive of patentability because the features argued are not set forth in the instant claims. Applicant's claim language does not set forth any specific steps for "quenching residual free radicals", therefor, the claim language reads on chemical methods for quenching free radicals, such as reaction with acetylene taught by Shalaby et al. Applicant's claim language does not specify the kind of irradiation or irradiation dose applied to the UHMWPE perform. The comprising language of the instant claims encompasses a step of incorporating UHMWPE fibers into a UHMWPE composite as taught by Shalaby et al.

It is agreed that Shalaby et al teach melting UHMWPE powder in contact with UHMWPE fibers to obtain a reinforced composite by heating for a time necessary to melt the

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powder and then cooling the composite. Shalaby et al disclose heating sheets of polymeric matrix and reinforcement to a temperature and for a time to melt the film and coat the reinforcement so that a unitary solid is produced upon cooling, corresponding to applicant's UHMWPE preform. The composite is then treated with high energy radiation in the presence of acetylene in order to sterilize and crosslink the composite UHMWPE. Radiation causes free radicals to form that are then "quenched" by crosslinking in the presence of acetylene. Thus the steps set forth in the instant claims are disclosed.

Applicant argues that neither Shalaby et al nor Sun et al discloses quenching free radicals formed upon irradiation. This argument is not persuasive for the following reasons. It is noted that the claim recitation "and quenching residual free radicals...preform" does not limit the manner of quenching free radicals. Shalaby et al clearly teach that high energy radiation crosslinks the UHMWPE in column 6, lines 1-7. Furthermore, Shalaby et al teach that the composite can be irradiated in the presence of acetylene which would be expected to enhance crosslinking (recombination of free radicals). Shalaby et al teach that the crosslinked UHMWPE composites may be irradiation sterilized without decline in physical properties, thus teaching that free radicals have been quenched in the disclosed process (column 2, lines 45-58). Sun et al specifically teach quenching free radicals remaining after irradiation by heat treatment followed by cooling (column 6, lines 48-51, and column 8, lines 11-20). No evidence to the contrary has been made of record.

Double Patenting Rejections: The double patenting rejections of record are maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-127 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby et al (5,824,411). Shalaby et al disclose a method that comprises melting an UHMWPE “construct polymer-fiber” and irradiating the resulting composite with high energy radiation to sterilize and crosslink composites of the UHMWPE. See column 2, lines 11-27, column 3, lines 9-18, column 5, line 32, to column 6, line 10, and Examples 1 and 5. Shalaby et al disclose heating sheets of polymeric matrix and reinforcement to a temperature and for a time to melt the film and coat the reinforcement so that a unitary solid is produced upon cooling. The composite is then treated with high energy radiation in the presence of acetylene in order to sterilize and crosslink the composite UHMWPE. Radiation causes free radicals to form that are then “quenched” by crosslinking in the presence of acetylene.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 124-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049). Sun et al teach a method for forming a medical implant comprising annealing a medical implant and then radiation sterilizing the implant. The irradiated implant is then further annealed to reduce free radicals. The difference from the instantly claimed process is that Sun et al teach treating a formed implant rather than a preform. It would have been obvious to one skilled in the art at the time of the invention to apply the process steps taught by Sun et al to a polyethylene preform. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of imparting the desirable properties taught by Sun et al to a preform material since the polymeric material is polyethylene in the implant and in the preform.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. irradiating and heating a polyethylene article, are set forth in the claims of '440 and in the instant claims. The instantly claimed step of heating to a temperature less than the decomposition temperature is considered to encompass the melting step set forth in the claims of '440. Alternatively, the melting step set forth in the claims of '440 corresponds to the step of quenching free radicals set forth in the instant claims and the comprising language of the claims of '440 encompasses the pre-annealing step in the instant claims. With respect to claims 126 and 127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129 and 135-137 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. With respect to claims 126-127, It would have been obvious to one skilled



in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '362 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 114 and 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. The step of heating above the melting temperature set forth in the

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claims of '089 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB  
7/2/2009

/Susan W Berman/  
Primary Examiner  
Art Unit 1796